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APPLICATION FOR LETTERS PATENT

BY

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FOR

THREADED FRUSTO-CONICAL INTERBODY

SPINAL FUSION IMPLANTS

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#### BACKGROUND OF THE INVENTION

##### Related Applications

This application is a continuation in part of copending United States application Serial No. 08/396,414 filed on February 27, 1995 which is a continuation-in-part of United States application Serial No. 08/074,781 filed on June 10, 1993, which is a continuation in part of United States application Serial No. 07/698,674 filed on May 10, 1991 which is a divisional of application Serial No. 07/205,935 filed on June 13, 1988, now United States Patent No. 5,015,247, all of which are incorporated herein by reference.

This application is also a continuation-in-part of United States application Serial No. 08/390,131 entitled Interbody Spinal Fusion Implants filed on February 17, 1995.

##### Field of the Invention

The present invention relates generally to interbody spinal fusion implants, and in particular to spinal fusion implants configured to restore and maintain two adjacent vertebrae of the spine in anatomical lordosis.

##### Description of The Related Art

Interbody spinal fusion refers to the method of achieving bony bridging between adjacent vertebrae through the disc space, the space between adjacent vertebrae normally occupied by a spinal disc. Numerous implants to facilitate such a fusion have been described by Cloward, Brantigan, and others, and are known to those skilled in the art. Generally, cylindrical implants offer the advantage of conforming to an easily prepared recipient bore spanning the disc space and penetrating into each of the adjacent vertebrae. Such a bore may be created by use of a drill. It is an anatomical fact that both the cervical spine and the lumbar spine are normally lordotic, that is convex forward. Such alignment is important to the proper functioning of the spine. Commonly, those conditions which require treatment by spinal fusion are associated

with a loss of lordosis.

Therefore, there exists a need for spinal fusion implants that permit for the restoration of anatomical lordosis.

#### SUMMARY OF THE INVENTION

The present invention is directed to a variety of interbody spinal fusion implants having at least a partially frusto-conical configuration. In the preferred embodiment, the spinal fusion implants of the present invention have a body that is partially or fully frusto-conical shape substantially along the portion of the implant in contact with the adjacent vertebrae of the spine. The spinal fusion implants of the present invention have an external thread for engaging the adjacent vertebrae of the spine and have an insertion end and a trailing end. The external thread may have a variable or constant thread radius and/or a constant or variable thread height measured from the body of the implant.

The spinal fusion implants of the present invention may be further modified so that while the upper and lower surfaces are portions of a frusto-cone, at least one side portion may be truncated to form a planar surface that is parallel to the central longitudinal axis of the implant to form straight walls. These implants may have a more tapered aspect at the insertion end of the implant to facilitate insertion. The spinal fusion implants of the present invention may be relatively solid and/or porous and/or hollow, and may have surface roughenings to promote bone ingrowth and stability.

The spinal fusion implants of the present invention may have wells extending into the material of the implant from the surface for the purpose of holding fusion promoting materials and to provide for areas of bone ingrowth fixation. These wells, or holes, may pass either into or through the implant and may or may not intersect. The spinal fusion implants of the present invention may have at least one chamber which may be in communication through at least one opening to the surface of the implant. Said chamber

may have at least one access opening for loading the chamber with fusion promoting substances. The access opening may be capable of being closed with a cap or similar means.

The spinal fusion implants of the present invention offer significant advantages over the prior art implants:

1. Because the spinal fusion implants of the present invention are at least partially frusto-conical in shape, those that taper from the leading edge to the trailing edge are easy to introduce and easy to fully insert into the spinal segment to be fused. In another embodiment, where the trailing edge of the implant is larger than the leading edge, the implant utilizes a tapered forward portion and an increasing thread height relative to the body from the leading edge to the trailing edge to facilitate insertion.
2. The shape of the implants of the present invention is consistent with the shape of the disc, which the implants at least in part replace, wherein the front of the disc is normally taller than the back of the disc, which allows for normal lordosis. The implants of the present invention are similarly taller anteriorly than they are posteriorly.
3. The spinal fusion implants of the present invention conform to a geometric shape, which shape is readily producible at the site of fusion, to receive said spinal fusion implants.

The spinal fusion implants of the present invention can be made of any material appropriate for human implantation and having the mechanical properties sufficient to be utilized for the intended purpose of spinal fusion, including various metals such as cobalt chrome, stainless steel or titanium including its alloys, various plastics including those which are bio-absorbable, and various ceramics or combination sufficient for the intended

purpose. Further, the spinal fusion implants of the present invention may be made of a solid material, a mesh-like material, a porous material and may comprise, wholly or in part, materials capable of directly participating in the spinal fusion process, or be loaded with, composed of, treated or coated with chemical substances such as bone, morphogenic proteins, hydroxyapatite in any of its forms, and osteogenic proteins, to make them bioactive for the purpose of stimulating spinal fusion. The implants of the present invention may be wholly or in part bioabsorbable.

OBJECTS OF THE PRESENT INVENTION

It is an object of the present invention to provide a spinal fusion implant that is easily inserted into the spine, having a tapered leading end;

It is another object of the present invention to provide a spinal fusion implant that tapers in height from one end to the other consistent with the taper of a normal spinal disc;

It is yet another object of the present invention to provide a spinal fusion implant that is capable of maintaining anatomic alignment and lordosis of two adjacent vertebrae during the spinal fusion process;

It is still another object of the present invention to provide a spinal fusion implant that is self stabilizing within the spine;

It is yet another object of the present invention to provide a spinal fusion implant that is capable of providing stability between adjacent vertebrae when inserted;

It is still another object of the present invention to provide a spinal fusion implant that is capable of participating in the fusion process by containing, being composed of, or being treated with fusion promoting substances;

It is further another object of the present invention to provide a spinal fusion implant that is capable of spacing apart and supporting adjacent vertebrae during the spinal fusion process;

It is still further another object of the present

invention to provide a spinal fusion implant that is consistent in use with the preservation of a uniform thickness of the subchondral vertebral bone;

It is another object of the present invention to provide a spinal fusion implant having a shape which conforms to an easily produced complementary bore at the fusion site; and

It is a further object of the present invention to provide a frusto-conical spinal fusion implant which may be placed side by side adjacent to a second identical implant across the same disc space, such that the combined width of the two implants is less than sum of the individual heights of each implant.

It is a further object of the present invention to provide a frusto-conical spinal fusion implant which may be placed side by side adjacent to a second identical implant across the same disc space, such that the combined width of the two implants is less than sum of the individual lengths of each implant.

These and other objects of the present invention will become apparent from a review of the accompanying drawings and the detailed description of the drawings.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side elevational view of the spinal fusion implant of the present invention having a body that is frusto-conical with an external thread having a substantially uniform radius.

Figure 1A is an enlarged fragmentary view along line 1A of Figure 1 illustrating the surface configuration of the implant of Figure 1.

Figure 1B is an enlarged fragmentary view along line 1A of Figure 1 illustrating an alternative embodiment of the surface configuration of the implant of the present invention made of a cancellous material.

Figure 1C is a cross sectional view along lines 1C--1C of Figure 1B illustrating the alternative embodiment of the surface configuration of the implant of the present invention made of a

cancellous material.

Figure 1D is an enlarged fragmentary view along line 1A of Figure 1 illustrating an alternative embodiment of the surface configuration of the implant of the present invention made of a fibrous mesh-like material.

Figure 1E is a fragmentary view along line 1A of Figure 1 illustrating an alternative embodiment of the surface configuration of the implant of the present invention comprising a plurality of spaced apart posts.

Figure 1F is an enlarged fragmentary sectional view along lines 1F--1F of Figure 1E illustrating the surface configuration of the implant of Figure 1E.

Figure 2 is an alternative embodiment of the spinal fusion implant of the present invention having a frusto-conical body with an external thread radius and thread height that are not constant.

Figure 3 is a cross sectional view along line 3--3 of the implant of Figure 2.

Figure 4 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention.

Figure 5 is a side elevational view and partial cut-away of a segment of the spinal column in lordosis showing the spinal fusion implant of Figure 4 being implanted with a driving instrument from the posterior approach to the spinal column.

Figure 6 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention having a frusto-conical body and truncated sides.

Figure 7 is an end view along line 7--7 of the spinal fusion implant of Figure 6 shown placed beside a second identical implant shown in hidden line.

Figure 8 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention having a body with an irregular configuration.

DETAILED DESCRIPTION OF THE DRAWINGS

Referring to Figure 1, a side elevational view of the spinal fusion implant of the present invention generally referred to by numeral 20 is shown. The implant 20 has a body 22 that is frusto-conical in shape such that the body 22 has a diameter (root diameter) that is generally frusto-conical. The body 22 has an insertion end 24 and a trailing end 26. The insertion end 24 may include a tapered portion 25 to facilitate insertion of the spinal implant 20. In the preferred embodiment, when the implant 20 is inserted from the anterior aspect of the spine, the body 22 of the implant 20 has a maximum diameter at a point nearest to the trailing end 26 and a minimum diameter at a point nearest to the insertion end 24.

The implant 20 has an external thread 28 having a substantially uniform radius  $R_1$  measured from the central longitudinal axis  $L_1$  of the implant 20. The outer locus of the external thread 28 (major diameter) has an overall configuration that is substantially parallel to the longitudinal axis  $L_1$ . While the major diameter of the implant 20 is substantially uniform, the external thread 28 may be modified at the leading edge by having initially a reduced thread radius to facilitate insertion of the implant 20 and may also be modified to make the external thread 28 self-tapping. In the preferred embodiment, the external thread 28 has a first thread 30 of a lesser radius than the radius  $R_1$  of the remainder of the external thread 28 to facilitate insertion of the implant 20. The second thread 32 has a greater radius than the first thread 30, but is still shorter than the radius  $R_1$  of the remainder of the external thread 28 which is thereafter of constant radius.

The body 22 is frusto-conical substantially along the portion of the body 22 in contact with the adjacent vertebrae of the spine which allows for creating and maintaining the adjacent vertebrae of the spine in the appropriate angular relationship to each other in order to preserve and/or restore the normal anatomic lordosis of the spine. The substantially uniform radius  $R_1$  of the

external thread 28 of the implant 20 allows engaging the bone of the adjacent vertebrae in a position that counters the forces which tend to urge the implant 20 from between the adjacent vertebrae in the direction opposite to which the implant 20 was implanted. The greater thread height measured from the body 22 near the leading end 24 of the implant 20 provides greater purchase into the vertebral bone and again enhances the stability of the implant 20. Further, the configuration of the external thread 28 increases the surface area of the implant 20 in contact with the vertebrae to promote bone ingrowth.

The implant 20 has a recessed slot 34 at its trailing end 26 for receiving and engaging insertion instrumentation for inserting the implant 20. The recessed slot 34 has a threaded opening 36 for threadably attaching the implant 20 to instrumentation used for inserting the implant 20.

Referring to Figure 1A, the implant 20 has an outer surface 38 that is porous to present an irregular surface to the bone to promote bone ingrowth. The outer surface 38 is also able to hold fusion promoting materials and provides for an increased surface area to engage the bone in the fusion process and to provide further stability. The pores of the outer surfaces 38 are microscopic in size having a diameter that is less than 1mm, in the range of 50-1000 microns, with 250-500 microns being the preferred diameter. It is appreciated that the outer surface 38, and/or the entire implant 20, may comprise any other porous material or roughened surface sufficient to hold fusion promoting substances and/or allow for bone ingrowth and/or engage the bone during the fusion process. The implant 20 may be further coated with bioactive fusion promoting substances including, but not limited to, hydroxyapatite compounds, osteogenic proteins and bone morphogenic proteins. The implant 20 is shown as being solid, however it is appreciated that it can be made to be substantially hollow or hollow in part.

Referring to Figure 1B, an enlarged fragmentary view along line 1A of Figure 1 illustrating an alternative embodiment of

the surface configuration 38 of the implant of the present invention made of a cancellous material is shown. The cancellous material 50, similar in configuration to human cancellous bone, having interstices 52 such that the outer surface 38 has a configuration as shown in Figures 1B and 1C. As the implant of the present invention may be made entirely or in part of the cancellous material 50, the interstices 52 may be present in the outer surface 338 and/or within the entire implant to promote bone ingrowth and hold bone fusion promoting materials.

Referring to Figure 1D, an enlarged fragmentary view along line 1A of Figure 1 illustrating an alternative embodiment of the surface configuration of the implant of the present invention made of a fibrous mesh-like material is shown. The mesh-like material 60 comprises strands 62 that are formed and pressed together such that interstices 64, capable of retaining fusion promoting material and for allowing for bone ingrowth, are present between the strands in at least the outer surface 38 of implant of the present invention.

Referring to Figures 1E and 1F, a fragmentary view along line 1A of Figure 1 illustrating an alternative embodiment of the surface configuration 38 of the implant of the present invention comprising a plurality of spaced apart posts 70 is shown. The posts 70 have a head portion 72 of a larger diameter than the remainder of the posts 70, and each of the interstices 74 is the reverse configuration of the posts 72, having a bottom 76 that is wider than the entrance to the interstices 74. Such a configuration of the posts 70 and interstices 74 aids in the retention of bone material in the surface 38 of the implant and further assists in the locking of the implant into the bone fusion mass created from the bone ingrowth. As the bone ingrowth at the bottom 76 of the interstices is wider than the entrance, the bone ingrowth cannot exit from the entrance and is locked within the interstice 74. The surface of the implant provides for an improvement in the available amount of surface area which may be still further increased by rough finishing, flocking or otherwise

producing a non smooth surface.

In the preferred embodiment, the posts 70 have a maximum diameter in the range of approximately 0.1-2 mm and a height of approximately 0.1-2 mm and are spaced apart a distance of approximately 0.1-2 mm such that the interstices 74 have a width in the range of approximately 0.1 to 2 mm. The post sizes, shapes, and distributions may be varied within the same implant.

In the preferred embodiment, for use in the lumbar spine, the implant 20 has an overall length in the range of approximately 24 mm to 32 mm with 26 mm being the preferred length. The body 22 of the implant 20 has a root diameter at the insertion end 24 in the range of 8-20 mm, with 14-16 mm being the preferred root diameter at the insertion end, and a root diameter at the trailing end 26 in the range of 10-24 mm, with 16-18 mm being the preferred diameter at the trailing end 26, when said implants are used in pairs. When used singly in the lumbar spine, the preferred diameters would be larger.

In the preferred embodiment, the implant 20 has a thread radius  $R_1$  in the range of 6 mm to 12 mm, with 9-10 mm being the preferred radius  $R_1$ . For use in the cervical spine, the implant 20 has an overall length in the range of approximately 10-22 mm, with 12-14 mm being the preferred length. The body 22 of the implant 20 has a root diameter at the insertion end 24 in the range of 8-22 mm, with 16-18 mm being the preferred root diameter at the insertion end when used singly, and 8-10 mm when used in pairs. The body 22 of the implant 20 has a root diameter at the trailing end 26 in the range of 10-24 mm, with 18-20 mm being the preferred root diameter at the trailing end 26 when used singly, and 10-12 mm when used in pairs; a thread radius  $R_1$  in the range of approximately 4-12 mm, with 9-10 mm being the preferred radius  $R_1$  when inserted singularly and 5-7 mm when inserted side by side in pairs.

Referring to Figure 2, an alternative embodiment of

implant 20 is shown and generally referred to by the numeral 120. The implant 120 has a body 122 similar to body 122 of implant 120 and has an external thread 128 having a radius  $R_3$  measured from the central longitudinal axis  $L_3$  of the implant 120. The thread radius  $R_3$  is not constant throughout the length of the implant 120 and the external thread 128 has a thread height that is also not constant with respect to the body 122 of the implant 120. In the preferred embodiment, the implant 120 has an external thread 128 with a radius  $R_3$  that increases in size from the insertion end 124 to the trailing end 126 of the implant 120.

Referring to Figure 3, a cross sectional view along line 3--3 of the implant 120 is shown. The implant 120 has an outer wall 144 surrounding an internal chamber 146. The large and small openings 140 and 142 may pass through the outer wall 144 to communicate with the internal chamber 146. The internal chamber 146 may be filled with bone material or any natural or artificial bone growth material or fusion promoting material such that bone growth occurs from the vertebrae through the openings 140 and 142 to the material within internal chamber 146. While the openings 140 and 142 have been shown in the drawings as being circular, it is appreciated that the openings 140 and 142 may have any shape, size configuration or distribution, suitable for use in a spinal fusion implant without departing from the scope of the present invention.

The openings 140 and 142 are macroscopic in size having a diameter that is greater than 1 mm. The large openings 140 have a diameter in the range of 206 mm, with the preferred diameter being 3.5mm; and the small openings have a diameter in the range of 1-2 mm, with 1.5 mm being the preferred diameter.

The implant 120 has a cap 148 with a thread 150 that threadably attaches to the insertion end 124 of the spinal fusion implant 120. The cap 148 is removable to provide access to the internal chamber 146, such that the internal chamber 146 can be filled and hold any natural or artificial osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material.

Some examples of such materials are bone harvested from the patient, or bone growth inducing material such as, but not limited to, hydroxyapatite, hydroxyapatite tricalcium phosphate; or bone morphogenic protein. The cap 148 and/or the spinal fusion implant 120 may be made of any material appropriate for human implantation including metals such as cobalt chrome, stainless steel, titanium, plastics, ceramics, composites and/or may be made of, and/or filled, and/or coated with a bone ingrowth inducing material such as, but not limited to, hydroxyapatite or hydroxyapatite tricalcium phosphate or any other osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material. The cap 148 and the implant 120 may be partially or wholly bioabsorbable.

Referring to Figure 4, a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention generally referred to by numeral 520 is shown. The implant 520 has a body 522 having a root diameter that is frustoconical in the reverse direction as that of implant 20 shown in Figure 1, in order to preserve and/or restore lordosis in a segment of spinal column when inserted from the posterior aspect of the spine. The body 522 has an insertion end 524 and a trailing end 526. In the preferred embodiment, the body 522 of the implant 520 has a minimum diameter at a point nearest to the trailing end 526 and a maximum diameter at a point nearest to the insertion end 524. The insertion end 524 may have an anterior nose cone portion 530 presenting a tapered end to facilitate insertion.

The implant 520 has an external thread 528 having a substantially uniform radius  $R_e$  measured from the central longitudinal axis  $L_e$  of the implant 520, such that the external diameter of the external thread 528 (major diameter) has an overall configuration that is substantially parallel to the longitudinal axis  $L_e$ . It is appreciated that the thread 528 can have a major diameter that varies with respect to the longitudinal axis  $L_e$ , such that the major diameter may increase from the insertion end 524 to the trailing end 526 or the reverse. The external thread 528 has a thread height measured from the body 522 that increases from the

insertion end 524 to the trailing end 526.

Referring to Figure 5, a segment of the spinal column S is shown with the vertebrae V<sub>1</sub> and V<sub>2</sub> in lordosis and an implant 520 shown being inserted from the posterior aspect of the spinal column S with an instrument driver D. The implant 520 is inserted with the larger diameter insertion end 524 first in order to initially distract apart the vertebrae V<sub>1</sub> and V<sub>2</sub> which then angle toward each other posteriorly as the implant 520 is fully inserted. It is appreciated that the insertion of implant 520 does not require the adjacent vertebrae V<sub>1</sub> and V<sub>2</sub> to be placed in lordosis prior to insertion, as the full insertion of the implant 520 itself is capable of creating the desired lordotic angular relationship of the two vertebrae V<sub>1</sub> and V<sub>2</sub>.

In the preferred embodiment, for use in the lumbar spine, the implant 520 has an overall length in the range of approximately 24 mm to 30 mm, with 26 mm being the preferred length. The body 522 of the implant 520 has a root diameter at the insertion end 524 in the range of 12-22 mm, with 16 mm being the preferred root diameter at the insertion end, and a root diameter at the trailing end 526 in the range of 10-20 mm, with 14 mm being the preferred diameter at the trailing end 526. In the preferred embodiment, the implant 520 has a thread radius R<sub>6</sub> in the range of 6 mm to 12 mm, with 8 mm being the preferred radius R<sub>6</sub>.

Referring to Figure 6, an alternative embodiment of the spinal fusion implant of the present invention generally referred to by the numeral 620 and a partial fragmentary view of a second identical implant, generally referred to by the numeral 621 are shown. The implant 620 has a body 622 that is partially frusto-conical in shape similar to body 22 of implant 20 shown in Figure 1, and has an insertion end 624 and a trailing end 626. The body 622 of the implant 620 has truncated sides 670 and 672 forming planar surfaces that are parallel to the longitudinal axis L. In this manner, two implants 620 and 621 may be placed side by side, with one of the sides 670 or 672 of each implant with little space between them, such that the area of contact with the bone of the

adjacent vertebrae is maximized. It is appreciated that the body 622 may also be cylindrical in shape and have truncated sides 670 and 672.

The implant 620 has an external thread 628 having a radius  $R_e$  measured from the central longitudinal axis L, that may be constant, such that the major diameter or outer locus of the external thread 628 has an overall configuration that is substantially cylindrical. It is appreciated that the external thread 628 may have a thread radius  $R_t$  that is variable with respect to the longitudinal axis L, such that the major diameter or outer locus of the external thread 628 has an overall configuration that is substantially frusto-conical.

Referring to Figure 7, an end view of the implant 620 placed beside implant 621 is shown. The implant 620 has a thread radius that is substantially constant and has a thread height measured from the body 622 that is greater at the sides 670 and 672. In this manner, two implants 620 and 621 can be placed beside each other with the external thread 628 of each implant interdigitated allowing for closer adjacent placement of the two implants as a result of the substantial overlap of the external thread 628 at the side 670 or 672 of the implants.

Referring to Figure 8, an alternative embodiment of the implant of the present invention is shown and generally referred to by the numeral 700. The implant 700 is similar in configuration to implant 20 shown in Figure 1, except that the body 722 has an irregular configuration. The configuration of the body 722 has a root diameter D which is variable in size throughout the length of the implant 700 and, as shown in this embodiment, comprises larger diameter portions 750 and smaller diameter portions 752. It is appreciated that each of the large diameter portions 750 may be of the same or different diameter and each of the smaller diameter portions 752 may be of the same or different diameter.

The outer surface of the body 722 of implant 720 may be filled with fusion promoting substances such that the smaller diameter portions 752 may hold such fusion promoting substances.

If so filled, the composite of the implant 700 and the fusion promoting material could still produce an even external surface of the body 722 if so desired.

While the present invention has been described in detail with regards to the preferred embodiments, it is appreciated that other variations of the present invention may be devised which do not depart from the inventive concept of the present invention. In particular, it is appreciated that the various teachings described in regards to the specific embodiments herein may be combined in a variety of ways such that the features are not limited to the specific embodiments described above.

Each of the features disclosed in the various embodiments and their functional equivalents may be combined in any combination sufficient to achieve the purposes of the present invention as described herein.